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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/276,868	03/26/1999	MICHAEL SIMONS	BIS-043	2716

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EXAMINER

KAM, CHIH MIN

ART UNIT PAPER NUMBER

1653

DATE MAILED: 03/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/276,868

Applicant(s)

SIMONS ET AL.

Examiner

Chih-Min Kam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 December 2004.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-15 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 11-15 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____

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DETAILED ACTION

1. The Request for Continued Examination (RCE) filed December 23, 2004 under 37 CFR 1.114 is acknowledged. An action on the RCE follows.

Status of the Claims

2. Claims 11-15 are pending.

Applicants' amendment filed December 23, 2004 is acknowledged, and applicant's response has been fully considered. Claims 11 and 15 have been amended, thus claims 11-15 are examined.

Rejection Withdrawn

Claim Rejections-Obviousness Type Double Patenting

3. The previous rejection of claims 11-15, under judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 10-13 of copending application 10/391,155 (US 2004/0009463), is withdrawn in view of applicant's submission of a terminal disclaimer, and applicant's response at pages 15-16 in the amendment filed December 23, 2004.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 11-15 remain rejected under 35 U.S.C. 102(b) as being anticipated by Blecha *et al.* (WO 96-32129).

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Blecha *et al.* teach PR-39 and the truncated analogs such as PR-14, PR-19 and PR-26, some of the peptides can inhibit leukocyte superoxide anion production and attract leukocytes, thus can be used as medicaments that fight infection by attracting leukocytes to a wound site to restrict tissue damage (page 3). The truncated analog PR-14 (RRRPRPPYLPRPRP, Fig. 1) comprises the amino acid sequence of SEQ ID NO:4 (RRRPRPPYLPR, claim 13) or SEQ ID NO: 5 (RRRPRPPY, claim 14), and PR-19 (RRRPRPPYLPRPRPPFFP, Fig. 1) comprises the amino acid sequence of SEQ ID NO:3 (RRRPRPPYLPRPRPP, claim 12). These truncated analogs of PR-39 such as PR-14 and PR-19, which have the same structural features as the claimed PR-39 oligopeptides, e.g., having less than 26 amino acid residues, having N-terminal Arg-Arg-Arg, and having identical amino acid sequence to the N-terminal region of native PR-39 peptide, would be expected to have the characteristics, traits or properties of the claimed peptides cited in the claim (claims 11 and 15) since they have the same amino acid sequences as the claimed sequence of SEQ ID NO: 3, 4 or 5.

In response, applicants indicate that the rejection made by Examiner is based solely and exclusively upon the legal doctrine of “inherency”, and the basis of “inherency” requires a factual determination of whether those aspects of the claimed subject matter that are not taught in the single prior art reference-the missing descriptive information are known in the field of the inventions by practitioners ordinarily skilled in that technical area; the Examiner must demonstrate the prior art reference discloses and provides all the requisite elements and particular limitations defined by the claim, as well as identifies the resulting capabilities, properties and traits recited by the claim language with substantial certainty; and Blecha *et al.* teach the synthesized anti-microbial peptides such as PR-14, PR-19 and PR-26 peptides are

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analogs or truncated peptides of PR-39 peptide, however, only PR-26 peptide was found to have anti-microbial activity, the PR-14 and PR-19 analogs failed to show any anti-microbial activity, thus, among the peptide family of PR-39, only PR-26 peptide has anti-microbial activity, the PR-14 and PR-19 are not operative and functional. Therefore, Blecha *et al.* disclose inoperative and non-functional peptide structures, which do not have the requisite elements and limitations of applicants' claimed invention (pages 16-35 of the response).

The response has been fully considered, however, the argument is not found persuasive because Blecha *et al.* teach the same truncated PR-39 peptides (e.g., PR-14 and PR-19) as the oligopeptides cited in claims 12, 13 or 14 (e.g., peptides comprising SEQ ID NO:3, 4 or 5), and PR-14 and PR-19, which have the same structural features as the claimed PR-39 oligopeptides, e.g., having less than 26 amino acid residues, having N-terminal Arg-Arg-Arg, and having identical amino acid sequence to the N-terminal region of native PR-39 peptide, would be expected to have the same properties and traits as the claimed PR-39 oligopeptides. Although the peptides of PR-14 and PR-19 do not have anti-microbial activity against specific bacteria (e.g., *E. coli*) as indicated by Blecha *et al.*, this anti-microbial activity is only one biological activity being tested, the reference does not indicate the peptides of PR-14 and PR-19 are inoperative and non-functional in all biological activities. The properties of the claimed PR-39 oligopeptides such as inhibiting proteasome-mediated degradation, being pharmacologically active, or interacting in-situ with the $\alpha 7$ subunit of proteasomes in the cytoplasm of the cell would be expected for peptides of PR-14 and PR-19, since these peptides contain the same structures as the claimed PR-39 oligopeptides.

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5. Claims 11-15 are rejected under 35 U.S.C. 102(a) as being anticipated by Chan *et al.* (J. Biol. Chem. 273, 28978-28985 (October 1998)).

Chan *et al.* teach biologically active fragment of PR-39 (PR-39(15)), which contains the first 15 residues of PR-39 with a biotinylated cysteine residue added to the C-terminal end (page 28979, left column, second paragraph), is able to kill *Salmonella typhimurium* PhoP⁻ at 5 μ M in well diffusion assays and to binds multiple cytosolic proteins (page 28980, Fig. 4; claims 12-14). This PR-39(15) peptide, which has the same structural features as the claimed PR-39 oligopeptides (SEQ ID NOs: 3, 4 and 5), e.g., having less than 26 amino acid residues, having N-terminal Arg-Arg-Arg, and having identical amino acid sequence to the N-terminal region of native PR-39 peptide, would be expected to have the characteristics, traits or properties of the claimed peptides cited in the claim (claims 11 and 15).

Conclusion

6. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached at 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-272-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.
Patent Examiner

A handwritten signature in black ink, appearing to read 'CMK' followed by a stylized flourish.

CMK
March 2, 2005